DECLARATION UNDER 37 C.F.R. § 1.131 Examining Group 1617

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Frank C. Eisenschenk, Ph.D., Patent Attorney

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Examiner

Helen Nguyen

Art Unit

1615

Applicants

Michael B. Zemel, Hang Shi, Paula C. Zemel

Serial No.

09/654,357

Filed

September 1, 2000

For

Materials and Methods for the Treatment or Prevention of Obesity

Patent Application

Docket No. UTR-104

Serial No. 09/654,357

Commissioner of Patents and Trademarks Washington, D.C. 20231

DECLARATION UNDER 37 C.F.R. § 1.131

Sir:

DR. MICHAEL B. ZEMEL, DR. HANG SHI, AND DR. PAULA C. ZEMEL DECLARE:

- THAT we are co-inventors of the invention disclosed and claimed in U.S. 1. Application Serial No. 09/654,357.
- 2. THAT said invention was completed in the United States prior to January 2000, as shown by the following exhibits. We conceived and reduced to practice methods for the stimulation of lipolysis in animals by increasing the amounts of dietary calcium consumed by these animals. Dietary calcium is provided in the form of calcium carbonate or powdered non-fat milk. Exhibit 1 shows that increasing dietary calcium stimulates lipolysis. The effects of a high calcium diet on adipocyte lipolysis was assayed using a glycerol release assay as described in Example 2 of the above-identified patent application.

3. That Exhibit 1 is a copy of pages taken from a laboratory record created and maintained in the normal course of laboratory operations, prior to January 2000. The completion date of the experiments and analyses recorded in these laboratory notebook pages have been redacted. We hereby attest that these redacted dates are prior to the critical date.

We hereby further declare that all statements made herein of our own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

	Further, Declarants sayeth not.	
Ву:	Michael B. Zemel, Ph.D.	Date:
Ву:	Hang Shi, Ph.D.	Date:
Ву:	Paula C. Zemel Ph.D.	Date: 8-21-200/

1 D	<u> </u>	mol/I		•	
STD 1 STD 1 MLAA Site		0.000 SD=	J. 009	RGD=	0,488
SEL A MEAN JED 3	. 44 - 12,44 3 3,060	9, 550	0.009	RSD=	0.072
3TD 3 MEAN= STD 4 STD 4	3.078	5.000	0.026	RSD=	0.844
MEAN=	8.317	3D=	0.002	RSD=	0.024
PHO	on PYZG	LYCEROL			
10	1	mo 17/1			
0.65 T	$\frac{2.006}{1.095}$				
WAN=	2.000 2.088		0.007	RSD=	0.350
	2, 994 8, 394	SD≕ O.100	0.009	RSD=	0.30%
MEAN STO 4 STO 4	3,405 10,27	SD- 0.⊋50	0.016	RUD =	u. 19a
MLAN = S (D = 5	10.75 15.30	SD: 0.500	6.014	RSD-	0.130
MEAN= UTD 6 UTD 6	15.44	SD≔ 1.000	ი, ::30	RSD =	მ. სან
MCAN 1	15,44	3D- 0.074	n.009	RSD=	0.058
	0.074	SD =	0.006	PSD:	0.000
3 3/WEAN-	0.085 6.028 6.022	50± 0.143 0.143	0.000	RSD=	0,000
3 1 4	0.143 3.148 3.173	. SD=	0.000	RSD=	0.000
-29 MEAN= 5 5	-0.015 3.473 3.479	SD= 0.002 0.003	0.001		
6	0.002 5.089 5.085	0.092	0.000		
- المنظونية المنظمة	0.091 114_540	روو	0.000	RSD=	0.000 ′······
7	A 530	0 661			

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Ծ.000 €
           5.955 0.139
           5.933 0.138
                      SD=
                            0.000
                                    RSD = 0.000
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           5.941 0.139
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           3.782 0.019
                            0.000
                                    RSD= 0.000
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           6.035 Ŭ.144
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                                    RSD= 0.000
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052 - SD
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5.045 0.089
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5.008 0.087

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             3.410-0.001L
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                                     RSD= 0.000
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            3.113-0.017L
  Tame -0.009
                       SD=
                             0.01:
                                     RSD=-122.2
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         36
             2.348-0.060L
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                                    RSD= 0.000
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            3.067-0.020L
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                      SD=
                            0.000
                                    RSD= 0.000
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             2.652-0.0431.
        30.
            2.640-0.044L
  午台MEAN=
           -U.044
                      3D=
                            0.000
                                    RSD= 0.000
        41)
            2,802-0,0051
        40
            2.746-0.6381.
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                      3D --
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                      SD=
                            0.012
                                    RSD= 14.28
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            5.577 0.118
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                                    RSD= 0.840
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            3.652 0.012
 DE MEAN=
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                            0.000
                                    RSD - 0.000
       44
            5.07/ 0.001
            5.000 0.090
       44
 0.090
                      SD≕
                           0.000
                                   RSD = 0.000
       45
            3.980 0.030
       45
            3.985 0.031
フら MEAN=
            0.030
                           0.000
                                   RSD= 0.000
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            4.219 0.044
       46
            4.212 0.043
&a MEAN=
           0.043
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                                   RSD= 0.000
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 &b MEAN=
           0.076
                           0.001
                                   RSD= 1.315
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       48
           4.955 0.084
 9amean=
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                                   RSD = 0.000
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4.082 0.036
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96 MEAN=
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                           0.001
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           5.004 0.087
                                  RSD = 0.000
O AMEAN=
           0.087
                           0.000
                     SD=
       51
           4.033 0.033
       51
           4.046 0.034
IUb Mean=
           0.033
                           0.000
                                  RSD= 0.000
                     SD-
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           4.807 0.076
      52
           4.792 0.075
1 QMEAN=
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                                  RSD = 0.000
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      53
           5.044 0.089
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            4.999 0.087
     50 - 5.004 0.087
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                            0.000
                                    RSD = 0.000
            4.033 0.033
       51
       51
            4.046 0.034
    MEAN=
            0.033
                      Sb∸
                            0.000
                                    RSD= 0.000
       52
            4.307 0.076
       52
            4.792 0.075
11 a MEAN=
            0.075
                      SD=
                            0.000
                                    RSD= 0.000
       53
            5.049 0.089
       53
            5.044 0.089
115 MEAN=
           0.089
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                           0.000
                                   RSD = 0.000
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       54
           5.674 0.124
   MEAN=
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                      SD=
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                                    RSD= 0.000
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           5.793 0.130
12-5MEAN=
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                                   RSD= 0.763
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           5.551 0.117
      56
           5.523 0.115
13aMEAN=
           U.116
                     SD=
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                                   RSD= 0.862
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     5.7
           3.551 0.007
136MEAN=
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                     SD≔
                           0.000
                                   RSD= 0.000
      58
           6.217 0.154
      53
           6.194 0.153
14ameax=
           0.153
                     SD=
                           0. ŭuu
                                   RSD= 0.000
      59
           1.984-0.080L
      59
          1.982-0.080L
ST MEAN=
          -0.080
                     SD=
                           0.000
                                   RSD= 0.000
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          5.393 0.108
      60
          5.395 0.108
| SaMEAN=
          0.108
                     SD≔
                           0.000
                                   RSD= 0.000
      61
          5.405 0.110
      5 i
          5.424 0.110
55<sub>MEANE</sub>
          0.110
                    SD=
                          0.000
                                  RSD= 0.000
      62
          2.896-0.029L
      62
          2.897-0.029L
bane AN=
         -0.029
                    SD=
    · 63
                          0.000
                                  RSD = 0.000
          5.112 0.093
     63
          5.154 0.095
   MEAN=
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                    SD=
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                                  RSD = 0.000
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          5.859 0.134
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          0.134
                    SD=:
                          0.000
                                  RSD≈ 0.000
     66
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     55
          5.011 0.087
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          0.087
                    SD=
                          0.000
                                  RSD= 0.000
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          5.401 0.109
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          5.413 0.109
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                                  RSD= 0.000
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                                  RSD= 1.470
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         5.256 0.101
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                         0.007
                                  RSD= 6.603
   金70 ~2.213-0.067L
   70 2 209-0.067L
AN 5-0 067 SD=
71 5 759 0.129
                         0.000
                                 RSD= 0.000
                                 RSD= 0.781
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•	8	0.221	0.1988	1.11167		• , ,		
	C	0.22 1	0.1000	0.947136				
♣ ACT	H(100nM)	١		0.377 100				
con	11(10011111	,						
1a		0.038	0.3977	0.095549				
1b		0.057	0.3636	0.156766				
2a		0.058	0.4902					
2b		0.000	0.4441	0.110010				
3b		0.056	0.3771	0.148502				
. 4a		0.035	0.5005	0.06993		,		
4b		0.006	0.5643	0.00333	0.010633			
- avg		0.000	0.5045	0.117813	0.010033			
	-Ca			0.117613				
, high 5a	-Ca	0.017	0.4475		0.037989			
5a		0.017	0.4473	0.536039	0.037969			
- 6a		0.177	0.3302					
		0.21		0.458916				
6b			0.4078	0.183914				
7a 7b		0.174	0.3832	0.454071				
7b		0.098	0.5349	0.183212				
8a		0.115	0.4088	0.281311				
8b		0.154	0.2215	0.69526				
avg	um dain.			0.39896				
	um-dairy	0.166	0.5204	0.242074				
9 a 9b		0.166	0.5304	0.312971				
10a		0.107 0.169	0.4747	0.225406				
10a			0.53	0.318868				
		0.103	0.5327	0.193355				
11a		0.155	0.3235	0.479134				
11b 12a		0.172	0.3931	0.437548				•
12a 12b		0.216 0.226	0.2288 0.2761	0.944056				
		0.226	0.2761	0.818544				
avg	daia.			0.466235				
high-	dairy	0.207	0.2045	0.504745				
13a		0.207		0.524715				
13b		0.069		0.172543				
14a		0.253		0.824104				
14b		0.237	0.2847	0.832455				
15a		0.196	0.2033	0.964092				*
15b		0.198	0.3495	0.566524	0.054545			
16a		0.023	0.4219	0.400500	0.054515			
16b		0.18	0.4152	0.433526 0.616851				
avg								